Study Title:	A Single Arm Trial of Adjuvant Pembrolizumab in Patients with Limited Stage Small Cell Lung Cancer	
Version Date:	11 April 2024	
PI:	Ryan Whitaker, MD, PhD	NCT06140407

Name of participant: _____ Age: _____

The following is given to you to tell you about this research study. Please read this form with care and ask any questions you may have about this study. Your questions will be answered. Also, you will be given a copy of this consent form.

Key Information:
The first section of this document contains some key points that the research team thought you would find important. The study is described in more detail after this section. If you do not understand something, please ask someone.

Key information about this study:
You are being asked to participate in this research study because you have a type of lung cancer called limited stage small cell lung cancer (LS-SCLC). For this condition, you are scheduled to receive standard treatment with radiation plus the following chemotherapy drugs: cisplatin or carboplatin, plus etoposide.

In this study (after you complete radiation and chemotherapy with cisplatin or carboplatin, plus etoposide), your doctor feels you may possibly benefit from investigational treatment with an antibody called pembrolizumab.

Investigational means that pembrolizumab is being tested in research studies and is not approved as a standard treatment for small cell lung cancer (SCLC) by regulatory health authorities, such as the U.S. Food and Drug Administration (FDA).

Pembrolizumab (also known as KEYTRUDA®) is an anti-PD-1 antibody currently approved by the FDA for treatment of non-small cell lung cancer (NSCLC) as well as several other cancers. Pembrolizumab increases the activity of cells (T cells) in the body's immune system. This happens when the pembrolizumab antibody binds to and blocks a protein receptor (called PD-1) located on the surface of T cells.

In this study it is hoped that investigational treatment with pembrolizumab received after standard radiation plus chemotherapy against small cell lung cancer (SCLC) will increase the ability of your immune system to fight your disease.

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It is unknown if this study will help you. You may have side effects from the study treatment and feel worse. Your disease may or may not respond to this investigational study treatment.

Pembrolizumab is an intravenous medication which you will be scheduled to receive once every three weeks (21 days) by intravenous (IV) infusion into your vein.

The length of time you receive treatment on this study will depend on the side effects you may experience, and how your disease does or does not respond to the study treatment. It is anticipated you may receive study treatment until you have intolerable side effects, until your disease gets worse, or for up to 1 year of pembrolizumab treatment on this study. You also may withdraw from the study at any time.

If you have side effects, your study doctor may require you to temporarily stop pembrolizumab. If you have serious side effects, you may be required to permanently stop pembrolizumab and discontinue participation in the study.

This study receives financial support from Merck & Co., Inc. (the pharmaceutical company that makes pembrolizumab).

During your participation in this study, pembrolizumab will be provided by the study at no cost to you. Because radiation and cisplatin or carboplatin plus etoposide are standard treatments for your disease, you and/or your insurance will be responsible for the cost of these treatments, as well as the usual care you would receive even if you were not participating in this study.

Up to about 20 patients are anticipated to enroll in this study at Vanderbilt.

Detailed Information:
The rest of this document includes detailed information about this study (in addition to the information listed above).

You do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services, or other rights. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study. Your medical record will

contain a note saying you are in a research study and may contain some research information about you. Anyone you authorize to receive your medical record will also get this information.
After first completing standard radiation plus chemotherapy with cisplatin or carboplatin, plus etoposide; all patients in this study are scheduled to receive investigational treatment with pembrolizumab in cycles lasting 21 days (3 weeks) per cycle:

- On Days 1, 2 and 3 of study Cycles 1, 2, 3 and 4 (about 12 total weeks):
  All patients are scheduled to receive standard chemotherapy. Radiation will be completed during 3-4 weeks of this 12-week interval as standard treatment.
- On Day 1 of study Cycles 5 through 21 (about 51 total weeks):
  All patients are scheduled to receive investigational treatment with the pembrolizumab antibody (up to about 1 year; depending on any intolerable side effects to the study treatment, and how each patient's disease does or does not respond to study treatment).

Additional details about the study schedule are provided below.

Screening
You will have the following done, in order to determine if you are a good candidate for the study:

- Review of your general medical history including information about your disease and what previous treatments you may have received.
- You will be asked about your level of activity.
- Physical and dermatologic (skin) exam; and obtaining your body weight, height, and vital signs (blood pressure, heart rate, breathing rate, and temperature).
- You will be asked about and you should tell your study doctor about any problems you are having and the medicines you are taking, including prescription and over-the-counter medicines, vitamins, and herbal supplements.
- Collection of about 4 teaspoons of your blood for routine laboratory testing (including blood counts and blood chemistry, ability of your blood to clot, thyroid levels, viral testing, and levels of troponin and B-type natriuretic peptide [BNP] to check your heart).
- Urine test to check your kidney function and overall health (about ¼ cup of urine).
- If you are a woman capable of becoming pregnant, you will have either a urine or blood pregnancy test.
- Electrocardiogram (ECG) to check your heart's performance.
- To check the current state of your disease: computed tomography (CT) scan of your chest, positron emission tomography (PET) scan, and magnetic resonance imaging (MRI) scan of your brain.

- Collection of about 10 teaspoons of blood for research.
- Archival tumor tissue: If you agree, your study team may request samples of your existing archival biopsy tissue, if such tissue is available, from a biopsy or procedure that you have already had done. One purpose of these tumor samples is to perform research testing, in order to possibly determine if something in disease tissue from different patients could help predict how different forms of lung cancer may or may not respond to investigational treatment with pembrolizumab.

Cycle 1; Day 1

If you are eligible for the study, you will return to clinic to start the study treatment; the following things will be done:

- Physical and dermatologic (skin) exam and vital signs.
- Questions about any changes to your health and to your medications.
- Collection of about 10 teaspoons of blood for research.
- You will start standard chemotherapy treatment for your disease:
  - **Cisplatin** or **carboplatin**: intravenous (IV) infusion into a vein.
  - **Etoposide**: intravenous (IV) infusion into a vein.

Cycle 1; Day 2 and Day 3

- Standard chemotherapy treatment for your disease:
  - **Etoposide**: intravenous (IV) infusion into a vein.

Cycles 2, 3 and 4; Day 1

- Physical and dermatologic (skin) exam and vital signs.
- Questions about any side effects you are experiencing and any changes to your medications.
- Collection of about 2 teaspoons of your blood for routine laboratory testing (including blood counts and blood chemistry).
- Urine test to check your kidney function and overall health (about ¼ cup of urine).
- If you are a woman capable of becoming pregnant, you will have either a urine or blood pregnancy test.
- Collection of about 10 teaspoons of blood for research.
- Standard chemotherapy treatment for your disease:
  - **Cisplatin** or **carboplatin**: intravenous (IV) infusion into a vein

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Cycles 2, 3 and 4; Day 2 and Day 3

- Standard chemotherapy treatment for your disease:
  - **Etoposide**: intravenous (IV) infusion into a vein.

Cycles 5 thru 21; Day 1

- Physical and dermatologic (skin) exam and vital signs.
- Questions about any side effects you are experiencing and any changes to your medications.
- Collection of about 2 teaspoons of your blood for routine laboratory testing (including blood counts and blood chemistry).
- Urine test to check your kidney function and overall health (about ¼ cup of urine).
- If you are a woman capable of becoming pregnant, you will have either a urine or blood pregnancy test.
- Every 2 cycles (every 6 weeks): About 2 teaspoons of blood to check your thyroid levels.
- Every 3 cycles (every 9 weeks): About 10 teaspoons of blood for research.
- Every 4 cycles (every 12 weeks): Computed tomography (CT) scan of your chest to check your disease.
- At any time during the study: Magnetic resonance imaging (MRI) scan of your brain could be done, if needed for standard management of your condition (for example, if signs or symptoms you experience suggest that your disease may possibly have spread to your brain or central nervous system).
- Investigational antibody treatment for your disease, once every 3 weeks (21 days):
  - **Pembrolizumab**: intravenous (IV) infusion into a vein over about 30 minutes.

End of Treatment

In general, you may continue this study for up to approximately 1 year of study treatment with pembrolizumab, as long as you do not have serious side effects, and as long as your disease does not get worse. In order to safely stop the study, you will have the following things done when you permanently stop the study treatment:

- Physical and dermatologic (skin) exam and vital signs.
- Questions about any side effects you are experiencing, and about any changes to your medications and any new anti-cancer therapy you may have started.
- Collection of about 2 teaspoons of your blood for routine laboratory testing (including blood counts and blood chemistry; and thyroid levels).
- Urine test to check your kidney function and overall health (about ¼ cup of urine).
- If you are a woman capable of becoming pregnant, you will have either a urine or blood pregnancy test.

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- Collection of about 6 teaspoons of blood for research.

30-Day Follow-Up
Approximately 30 days after your final treatment in this study (or earlier if you begin new anti-cancer treatment after this study), you will have the following things done as part of follow-up:

- Physical and dermatologic (skin) exam and vital signs.
- Questions about any side effects you are experiencing, and about any changes to your medications and any new anti-cancer therapy you may have started.
- Collection of about 2 teaspoons of your blood for routine laboratory testing (including blood counts and blood chemistry).
- Urine test to check your kidney function and overall health (about ¼ cup of urine).
- If you are a woman capable of becoming pregnant, you will have either a urine or blood pregnancy test.

Long-term Follow-Up
About every 3 months (12 weeks) after your end of treatment or 30-Day follow-up visit in this study:

- Collection of about 4 teaspoons for routine laboratory testing and about 10 teaspoons of your blood for research.
- You and/or your doctor's office may be contacted, for example by telephone or a clinic visit, to check on how you are doing and to learn about any new anti-cancer therapy you may have started.

These long-term follow-up procedures are intended until one of the following occurs (whichever occurs first): study ends, you withdraw your consent, your death, or until 2 years after your final dose of pembrolizumab treatment in this study. Additional follow-up beyond two years may occur if deemed medically necessary by your study physician.

Side effects and risks that you can expect if you take part in this study:
You may have side effects while on this study. Everyone participating in the study will be watched carefully for any side effects. However, study doctors don't know all the side effects that may happen.

Side effects may be mild or very serious. Some side effects could begin soon after you begin the study treatment. Other side effects could be delayed and occur later in the study, or even after you stop the study treatment. Your health care team may give you medicines to help decrease the frequency or severity of side effects. In some cases, side effects can be serious, long lasting, or may never go away. There is also a risk of death.

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You should tell your study doctor or study nurse right away about any possible side effects that you experience while participating in this study. Getting medical treatment right away may help keep side effects from becoming more serious.

Risks of Pembrolizumab (also known as KEYTRUDA®)

Pembrolizumab can cause serious side effects. Pembrolizumab is a medicine that may treat certain cancers by working with your immune system. Pembrolizumab can cause your immune system to attack normal organs and tissues in any area of your body and can affect the way they work.

These problems can sometimes become severe or life-threatening and can lead to death.

You can have more than one of these problems at the same time. These problems may happen anytime during treatment or even after your treatment has ended.

Call or see your study doctor right away if you develop any new or worsening signs or symptoms, including:

Lung problems
- cough
- shortness of breath
- chest pain.

Intestinal problems
- diarrhea (loose stools) or more frequent bowel movements than usual
- stools that are black, tarry, sticky, or have blood or mucus
- severe stomach-area (abdomen) pain or tenderness
- inflammation of the stomach
- lack of enough pancreatic enzymes leading to poor digestion
- bloating, gas, discomfort in the stomach-area

Liver problems
- yellowing of your skin or the whites of your eyes
- severe nausea or vomiting
- pain on the right side of your stomach area (abdomen)
- dark urine (tea colored)

- bleeding or bruising more easily than normal.

Hormone gland problems

- headaches that will not go away or unusual headaches
- eye sensitivity to light
- eye problems
- rapid heartbeat
- increased sweating
- extreme tiredness
- weight gain or weight loss
- feeling more hungry or thirsty than usual
- urinating more often than usual
- hair loss
- feeling cold
- constipation
- your voice gets deeper
- dizziness or fainting
- changes in mood or behavior, such as decreased sex drive, irritability, or forgetfulness.

Kidney problems

- decrease in your amount of urine
- blood in your urine
- swelling of your ankles
- loss of appetite.

Skin problems

- rash
- itching
- skin blistering or peeling
- painful sores or ulcers in your mouth or in your nose, throat, or genital area
- fever or flu-like symptoms
- swollen lymph nodes.

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Problems can also happen in other organs and tissues. These are not all of the signs and symptoms of immune system problems that can happen with pembrolizumab. Call or see your study doctor right away for any new or worsening signs or symptoms, which may include:

- chest pain, irregular heartbeat, shortness of breath, swelling of ankles
- confusion, sleepiness, memory problems, changes in mood or behavior, stiff neck, balance problems, tingling or numbness of the arms or legs
- double vision, blurry vision, sensitivity to light, eye pain, changes in eyesight
- persistent or severe muscle pain or weakness, muscle cramps
- low red blood cells, bruising, feeling weak, lightheaded, shortness of breath (hemolytic anemia).

Infusion reactions that can sometimes be severe or life-threatening. Signs and symptoms of infusion reactions may include:

- chills or shaking
- dizziness
- itching or rash
- feeling like passing out
- flushing
- fever
- shortness of breath or wheezing
- back pain.

Common side effects of pembrolizumab when used alone include:

- feeling tired
- pain, including pain in muscles, bones or joints and stomach-area (abdominal) pain
- rash
- diarrhea
- fever
- cough
- decreased appetite
- itching
- shortness of breath
- constipation
- nausea

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- low levels of thyroid hormone.

Side effects of pembrolizumab when used alone that are more common in children than in adults include:

- fever
- vomiting
- upper respiratory tract infection
- headache
- low levels of white blood cells
- low levels of red blood cells (anemia).

Common side effects of pembrolizumab when given with certain chemotherapy medicines include:

- feeling tired or weak
- nausea
- constipation
- diarrhea
- decreased appetite
- rash
- vomiting
- cough
- trouble breathing
- fever
- hair loss
- inflammation of the nerves that may cause pain, weakness, and paralysis in the arms and legs
- swelling of the lining of the mouth, nose, eyes, throat, intestines, or vagina
- mouth sores
- headache
- weight loss
- stomach-area (abdominal) pain
- joint and muscle pain
- trouble sleeping.

Before receiving pembrolizumab, tell your study doctor about all of your medical conditions, including if you:

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- have immune system problems such as Crohn's disease, ulcerative colitis, or lupus
- have received an organ transplant
- have received or plan to receive a bone marrow (stem cell) transplant that uses donor stem cells (allogeneic)
- have received radiation treatment to your chest area
- have a condition that affects your nervous system, such as myasthenia gravis or Guillain-Barré syndrome
- are pregnant or plan to become pregnant.

Reproductive Health/Sexual Activity and Pregnancy

Some medications have the potential to cause side effects in the reproductive system of women or men that could cause harm, including birth defects, during pregnancy. Pembrolizumab can harm an unborn baby.

If sexually active with the ability to become pregnant or to cause pregnancy, both women and men participating in this study must agree to use effective birth control as discussed with and directed by their study doctor.

In the event of pregnancy, the study team may request additional information about the pregnancy or the outcome of the pregnancy in an effort to better understand the effects of study treatment on a pregnancy and/or the fetus.

Information for Women who could become pregnant (Women of Child-bearing Potential):

- Before starting treatment in this study, tell your study doctor if you are pregnant or plan to become pregnant.
- You will have a pregnancy test before starting treatment in this study.
- Together with your partner, you must use effective birth control during treatment in this study and for at least 120 days after your final dose of study treatment. Talk to your study doctor about birth control methods you can use during this time.
- Tell your study doctor right away if you think you may be pregnant, or if you become pregnant during treatment in this study.

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- Tell your study doctor if you are breastfeeding or plan to breastfeed. It is not known if the study treatment passes into your breast milk. Do not breastfeed during treatment in this study and for at least 120 days after your final dose of study treatment.

Information for Men with sexual partners who could become pregnant (Partners of Childbearing Potential):

From the time you start treatment in this study until at least 120 days after your final dose of study treatment you must:

- Tell your sexual partner about your participation in this clinical trial. Together with your partner, you must use effective birth control during treatment in this study and for at least 120 days after your final dose of study treatment. Talk to your study doctor about birth control methods you can use during this time.
- Tell your study doctor immediately if your partner becomes pregnant during this clinical trial.

Risks of Procedures

Blood Collection
Risks of taking blood include pain, a bruise at the point where blood is taken, redness and swelling of the vein, infection, and a rare risk of fainting.

Electrocardiogram (ECG)
An ECG is a test that measures the heart's electrical activity. You will typically be asked to lie flat on a table and several small electrode pads (like stickers) will be placed on your body. This test usually takes about 10 minutes. The test may cause some redness or itching where the pads are placed.

Radiation
This research study involves exposure to radiation from 1 PET/CT scan. This radiation exposure is not necessary for your medical care and is for research purposes only. The total amount of radiation that you will receive by participating in this study is equal to your body receiving 78 months (6.5 years) of radiation from your natural surroundings or about 39% of the amount allowed in a year for people who are exposed to radiation as part of their work.

To protect your bladder from the effects of the injected radioactive substances, you should drink plenty of fluids and empty your bladder every two hours for at least the first six hours after you have each PET/CT scan.

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Computed Tomography (CT Scan)

A CT scan uses radiation (x-rays) guided by a computer to take pictures of your internal organs. The contrast solution that may be given for a CT scan may cause an allergic reaction (rare). Severe allergic reactions can be life threatening. CT contrast solution can cause kidney damage, especially if you are diabetic, dehydrated (lost body water) or elderly. CT contrast is used in scans to highlight specific parts of the body.

During CT scans, you will lie still on a table that slides into a tunnel slightly wider than your body. People who feel anxiety in confined spaces (claustrophobia) may feel uncomfortable in the narrow cylinder. If you feel uncomfortable in confined spaces, please tell your study doctor and the imaging team performing your scans. They may give you a medication in an effort to make you feel more comfortable in a confined space.

Positron Emission Tomography (PET Scan)

A PET scan uses a small amount of radioactive glucose (sugar) and a computer to create images of how organs and tissues in the body are functioning. PET imaging is often used to look for and take pictures of disease in the body, based on the concept that abnormal cells in the body use glucose sugar at a different rate than normal cells. This allows the PET scanner to create a detailed picture of how the body is working at a particular time.
The radioactive tracer used during a PET scan is given through a vein (IV). The needle is most often inserted on the inside of your elbow. The tracer travels through your blood and collects in organs and tissues. This helps the radiologist see certain areas more clearly.

You will need to wait as the tracer is absorbed by your body. This often takes about 1 hour. Then, you will lie on a narrow table that slides into a large tunnel-shaped scanner. The PET scan detects signals from the tracer. A computer changes the signals into 3D pictures. The images are displayed on a monitor for your health care provider to read.

You must lie still during the test. Too much movement can blur images and cause errors. How long the test takes depends on what part of the body is being scanned.

Side effects associated with radiotracers include pain at IV site, infection, bleeding, low blood pressure, changes in blood sugar levels, and allergic reactions.

Magnetic Resonance Imaging (MRI Scan)

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An MRI is a type of scan using magnets to make a picture of the body and identify areas that could be injured or suspicious for diseases such as cancer. Some people cannot have an MRI because they have some type of metal in their body. For example, if you have a heart pacemaker, artificial heart val ves, metal implants such as metal ear implants, pieces or fragments of bullets or shrapnel, chemotherapy or insulin pumps, or any other metal such as metal clips or rings, you cannot have an MRI.

During an MRI, you will lie in a small closed area usually inside a large magnetic tube. Some people are scared or anxious in small places (claustrophobic). The MRI scanner makes loud banging noises while taking a measurement, so either ear plugs or specially designed headphones will be used to reduce the noise.

Intravenous (IV) Catheter
Prior to beginning pembrolizumab, your study doctor may need to insert an intravenous (IV) catheter for the delivery of pembrolizumab and to take blood samples. IV catheters can usually be placed in a hand, arm, or leg. These are known as "peripheral" IVs. IVs placed in the central circulation, like the internal jugular vein (neck) or subclavian vein (just beneath the collar bone), are known as "central lines." You should discuss this with your study doctor. For both types of intravenous catheter, the area will be numbed (with an anesthetic) before the catheter is inserted. During the insertion, you could feel a pinch and shortly thereafter bleeding, redness, or a bruise could develop. Rarely, an infection could occur if not kept clean. For central catheters, although rare, they can sometimes cause collapse of a lung or cause bleeding. Lung collapse is usually treated by putting a tube into your chest for a few days to allow your lung to expand. Pressure is placed on any area that might bleed.

Risks that are not known:
Because this treatment is investigational, meaning non-FDA approved, there may be risks that we do not know about at this time.

Good effects that might result from this study:
The benefits to science and humankind that might result from this study: Participating in this study may help patients with cancer get better care in the future.

The benefits you might get from being in this study: Participating in this study may or may not have direct medical benefit for you. Pembrolizumab is being tested in research studies and is not approved as a standard treatment for small cell lung cancer (SCLC) by regulatory health authorities, such as the U.S. Food and Drug Administration (FDA). You may or may not receive therapeutic benefit from participation in this study. Your condition may get better but it could stay the same or get worse.

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Payments for your time spent taking part in this study or expenses:
You will not be paid for your participation in this study.

Costs to you if you take part in this study:
If you agree to take part in this research study, you and/or your insurance will not have to pay for the tests and treatments that are being done only for research. However, you are still responsible for paying for the usual care you would normally receive for the treatment of your illness. This includes treatments and tests you would need even if you were not in this study. These costs will be billed to you and/or your insurance.

You have the right to ask what it may cost you to take part in this study. If you would like assistance, financial counseling is available through the Vanderbilt Financial Assistance Program. The study staff can help you contact this program. You have the right to contact your insurance company to discuss the costs of your routine care (non-research) further before choosing to be in the study. You may choose not to be in this study if your insurance does not pay for your routine care (non-research) costs and your doctor will discuss other treatment plans with you.

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Payment in case you are injured because of this research study:
If it is determined by Vanderbilt and the Investigator that an injury occurred, then you and/or your insurance may be billed for the cost of medical care provided at Vanderbilt to treat the injury. You will be responsible for any copayments or deductibles associated with the treatment of that injury.

There are no plans for Vanderbilt to pay for the costs of any additional care. There are no plans for Vanderbilt to give you money for the injury.

Who to call for any questions or in case you are injured:
If you should have any questions about this research study or if you feel you have been hurt by being a part of this study, please feel free to contact Dr. Ryan Whitaker at [redacted]. If you cannot reach the research staff, please page the study doctor at (615) 322-5000.

For additional information about giving consent or your rights as a person in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to call the VUMC Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

Reasons why the study doctor may take you out of this study:
Your study doctor might take you out of the study for reasons such as:

- You are unable to tolerate the treatment, or you have a side effect and the study doctor feels should end the treatment.
- Your disease spreads or gets worse (progresses).
- You have another serious illness or need major surgery.
- You do not follow the study doctor's instructions.
- Your health changes or new information becomes available and the study doctor feels it is no longer in your best interest for you to continue in the study, or decides to stop the study.

If you are removed from the study, the reason will be explained to you.

What will happen if you decide to stop being in this study?
If you decide to stop being part of the study, you should tell your study doctor. Deciding to not be part of the study will not change your regular medical care in any way.

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Clinical Trials Registry:
A description of this clinical trial will be available on www.clinicaltrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this Web site at any time.

Clinical Trials Reporting Program.
Vanderbilt's NCI-Designated Cancer Center or the Sponsor registers National Cancer Institute (NCI)-supported clinical trials with NCI though their Clinical Trials Reporting Program (CTRP) to provide study related information. The data provided will include the following identifiable information that may identify you: birth month/year and five-digit zip code. NCI uses the data to manage and enhance the nation's investment in cancer research.

Confidentiality:
All efforts within reason will be made to keep your personal information in your research record confidential but total confidentiality cannot be guaranteed. Your information and samples will be given a code. Dr. Whitaker, his staff, and other authorized people will be the only people who know your personal information.

Study data will be recorded in a Vanderbilt electronic database which is maintained by a research coordinator and data manager at Vanderbilt. The electronic database is password protected in order to help protect your identity. Your study records will be locked up in the clinical trials office. Vanderbilt may share your information, without identifiers, to others or use it for other research projects not listed in this form. Vanderbilt, Dr. Whitaker, and his staff will comply with any and all laws regarding the privacy of such information. There are no plans to pay you for the use or transfer of this de-identified information.

Privacy:
Any samples and information about you may be made available to others to use for research. To protect your privacy, we will not release your name. You will not receive any benefit as a result of the tests done on your samples. These tests may help us or other researchers learn more about the causes, risks, treatments, or how to prevent this and other health problems.

Your samples may be used to make new products or tests. These may have value and may be developed and owned by the study staff, Vanderbilt University, Vanderbilt University Medical Center, and/or others. If this happens, there are no plans to provide money to you.

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At any time, you may ask to have your sample destroyed. You should contact Dr. Whitaker to have your sample destroyed and no longer used for research. His mailing address is:

[redacted]

We will not be able to destroy research data that has already been gathered using your sample. Also, if your identity was removed from the samples, we will not be able to locate and destroy them.

There will be no costs to you for any of the tests done on your samples. You will not be paid for the use of your samples.

Authorization to Use/Disclose Protected Health Information
What information is being collected, used, or shared?
To do this research, we will need to collect, use, and share your private health information. By signing this document, you agree that your health care providers (including both Vanderbilt University Medical Center and others) may release your private health information to us, and that we may use any and all of your information that the study team believes it needs to conduct the study. Your private information may include things learned from the procedures described in this consent form, as well as information from your medical record (which may include information such as HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

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Who will see, use or share the information?
The people who may request, receive or use your private health information include the researchers and their staff. Additionally, we may share your information with other people at Vanderbilt, for example if needed for your clinical care or study oversight. By signing this form, you give permission to the research team to share your information with others outside of Vanderbilt University Medical Center. This may include the sponsor of the study and its agents or contractors, outside providers, study safety monitors, government agencies, other sites in the study, data managers and other agents and contractors used by the study team. We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee that your information will not be shared with others. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may no longer protect it.

Do you have to sign this Authorization?
You do not have to sign this Authorization, but if you do not, you may not join the study.

How long will your information be used or shared?
Your Authorization for the collection, use, and sharing of your information does not expire. Additionally, you agree that your information may be used for similar or related future research studies.

What if you change your mind?
You may change your mind and cancel this Authorization at any time. If you cancel, you must contact the Principal Investigator in writing to let him know by using the contact information provided in this consent form.

Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization.

You have the right to see and copy the PHI we gather on you for as long as the study doctor or research site holds this data. To ensure the scientific quality of the research study, you will not be able to review some of your research data until after the research study is finished.

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

Study Title:	A Single Arm Trial of Adjuvant Pembrolizumab in Patients with Limited Stage Small Cell Lung Cancer
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STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY

I have read this consent form and the research study has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to take part in this study.

Date _____ Signature of patient/volunteer _____

Consent obtained by:

Date _____ Signature _____

Printed Name and Title _____

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Consent for Genetic Research

A purpose of this study is to look at genes (DNA) and how they affect health and disease. Genes are the instruction manual for your body. The genes you get from your parents decide what you look like and how your body behaves. They can also tell us a person's risk for certain diseases and how they will respond to treatment.

Patients with similar diseases do not always obtain the same benefit from the same treatment. Therefore, a goal is to help understand why patients respond differently to treatment, and to then develop treatment that provides maximum benefit for individual patients.

As part of the study, your blood and/or fluid samples and tumor biopsy tissue will be collected to better understand your disease. It is possible that genetic testing may be conducted on some or all of this material. You are being asked for your permission to allow this.

It is possible that genetic testing on these samples could help to learn more about:

- The effect of treatment on your body
- Why some people respond to treatment and others do not
- Why some people have side effects
- The causes of the disease.

What we learn about you from research on your samples is unlikely to be put in your health record. No one else (like a relative, boss, or insurance company) will be given your test results.

One risk of giving samples for this research may be the release of your name that could link you to the stored samples and/or the results of the tests run on your samples. This may cause problems with insurance or getting a job. To help prevent this, these samples will be given a code. Only the study staff will know the code. The name that belongs to the code will be kept in a locked file or in a computer with a password. Dr. Whitaker and his staff helping with the study will have access to your name.

Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums. Employers with 15 or more employees may not use your genetic information that comes from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Your sample may be used to make DNA that will be kept for an unknown length of time (maybe years) for future research. Samples will be destroyed when no longer needed. Your samples may be used to make new products, tests or findings. These may have value and may be developed and owned by the study staff, Vanderbilt University, Vanderbilt University Medical Center, and/or others. If this happens, there are no plans to provide money to you.

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Your samples and information about you may be shared with others to use for research. To protect your privacy, we will not release your name. You will not receive any benefit as a result of the tests done on your samples. These tests may help us learn more about the causes, risks, treatments, or how to prevent this and other health problems.

At any time, you may ask to have your sample destroyed. You should contact Dr. Whitaker to have your sample destroyed and no longer used for research. His mailing address is:

[redacted]

We will not be able to destroy research data that has already been gathered using your sample. Also, if your identity was removed from the samples, we will not be able to locate and destroy them. There will be no costs to you for any of the tests done on your samples. You will not be paid for the use of your samples.

Please check Yes or No to the questions below. A question with only a 'Yes Box' indicates a required part of the study:

I agree that my study team can request optional samples of my existing ARCHIVAL biopsy tissue, if such tissue is available, from a biopsy or procedure that I have already had done:

☐ **Yes** ☐ **No**

My blood/tissue/fluid samples may be used for current gene research in cancer related to pembrolizumab:

☐ **Yes** ☐ **No**

My blood/tissue/fluid samples may be stored/shared for future gene research in cancer:

☐ **Yes** ☐ **No**

My blood/tissue/fluid samples may be stored/shared for future gene research for other health problems (such as arthritis, heart disease, etc):

☐ **Yes** ☐ **No**

Signature: _____ Date: _____